DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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November 12, 2014

Cook Vascular, Inc.
% Thomas Kardos
Vice President, Regulatory Affairs
1186 Montgomery Lane
Vandergrift, Pennsylvania 15690

Re: K142301
Trade/Device Name: Evolution Mechanical Dilator Sheath Set, Evolution Shortie Mechanical Dilator Sheath Set, SteadySheath Evolution Tissue Stabilization Sheath, SteadySheath Evolution Shortie Tissue Stabilization Sheath
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator for Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: August 15, 2014
Received: August 18, 2014

Dear Thomas Kardos,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142301

Device Name: Evolution® Mechanical Dilator Sheath Set
Evolution® Shortie Mechanical Dilator Sheath Set
SteadySheath™ Evolution® Tissue Stabilization Sheath
SteadySheath™ Evolution® Shortie Tissue Stabilization Sheath

Indications for Use for the Evolution® Mechanical Dilator Sheath Set, Evolution® Shortie Mechanical Dilator Sheath Set, and SteadySheath™ Evolution® Tissue Stabilization Sheath:

The Evolution® Mechanical Dilator Sheath Set is intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects.

The Evolution® Shortie Mechanical Dilator Sheath Set is intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects.

The SteadySheath™ Evolution® Tissue Stabilization Sheath is intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects.

The SteadySheath™ Evolution® Shortie Tissue Stabilization Sheath is intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects.

Prescription Use X OR Over-the-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY: **K142301**

Submitted By: Thomas J. Kardos
Cook Vascular, Inc.
1186 Montgomery Lane
Vandergrift, PA 15690
Phone: (724) 845-8621 x2225
Fax: (724) 845-2848
Date Prepared: August 15, 2014

Device:

Trade Name:	Evolution® RL Controlled-Rotation Dilator Sheath Set Evolution® Shortie RL Controlled-Rotation Dilator Sheath Set SteadySheath™ Evolution® Tissue Stabilization Sheath SteadySheath™ Evolution® Shortie Tissue Stabilization Sheath
Common Name:	Vessel Dilator for Percutaneous Catheterization
Classification Name:	Dilator, Vessel, for Percutaneous Catheterization DRE (21 CFR §870.1310)

Indications for Use:

The Evolution® Mechanical Dilator Sheath Set, Evolution® Shortie Mechanical Dilator Sheath Set, SteadySheath™ Evolution® Tissue Stabilization Sheath, and SteadySheath™ Evolution® Shortie Tissue Stabilization Sheath are intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects.

Predicate Device:

The devices, subject of this submission, are substantially equivalent to the predicate devices, the Evolution® Mechanical Dilator Sheath Set, cleared on May 10, 2006 under 510(k) number K061000 and the Evolution® RL Controlled-Rotation Dilator Sheath Set and Evolution® Shortie RL Controlled-Rotation Dilator Sheath Set, cleared on July 1, 2014 under 510(k) number K141148.

Comparison to Predicate Device:

It has been demonstrated that the Evolution® Mechanical Dilator Sheath Set and Evolution® Shortie Mechanical Dilator Sheath Set are comparable to the predicate devices, and the SteadySheath™ Evolution® Tissue Stabilization Sheath and SteadySheath™ Evolution® Shortie Tissue Stabilization Sheath are comparable to the outer sheath of the predicate devices. The Evolution® Mechanical Dilator Sheath Set and Evolution® Shortie Mechanical Dilator Sheath Set are identical in terms of intended use, principles of operation, and basic technological characteristics to the predicate devices, and also identical in materials of construction to the predicate Evolution® RL Controlled-Rotation Dilator Sheath Set and Evolution® Shortie RL

Controlled-Rotation Dilator Sheath Set (K141148). The SteadySheath™ Evolution® Tissue Stabilization Sheath and SteadySheath™ Evolution® Shortie Tissue Stabilization Sheath are identical in terms of intended use, principles of operation, and basic technological characteristics to the outer sheaths of the predicate devices, and also contains only materials found in the predicate Evolution® RL Controlled-Rotation Dilator Sheath Set and Evolution® Shortie RL Controlled-Rotation Dilator Sheath Set (K141148). The safety and effectiveness of the modifications are supported by testing.

Device Description:

The Evolution® Mechanical Dilator Sheath Set is constructed of two coaxial sheaths connected to a handle capable of mechanically rotating the inner sheath. In use, the coaxial sheaths are advanced over an indwelling catheter or cardiac lead. The inner sheath (available in 9, 11, and 13 French diameters) is designed to rotate in a clockwise manner by pulling the trigger in the handle assembly. As the inner sheath is advanced, the rotation of the sheath assists in dilation of any binding tissue which may be anchoring the catheter or lead to the inner vascular or inner cardiac wall. The outer coaxial sheath can be used to stabilize the cardiac wall at the point of lead/catheter tip attachment to allow for detachment and removal (counter traction technique). The device has a working length of 40.6 centimeters.

The Evolution® Shortie Mechanical Dilator Sheath Set is constructed of two coaxial sheaths connected to a handle capable of mechanically rotating the inner sheath. The outer sheath has winged control tabs located at its proximal (handle) end. The sheaths are advanced over an indwelling catheter or cardiac lead. The inner sheath (available in 9 and 11 French diameters) is designed to rotate in clockwise manner by pulling the trigger in the handle assembly. As the inner sheath is advanced, the rotation of the sheath assists in dilation of any binding tissue which may be anchoring the catheter or lead to the inner vascular or inner cardiac wall. The outer coaxial sheath can be used to stabilize the cardiac wall at the point of lead/catheter tip attachment to allow for detachment and removal (counter traction technique). The device has a working length of 13.6 centimeters.

The SteadySheath™ Evolution® Tissue Stabilization Sheath and SteadySheath™ Evolution® Shortie Tissue Stabilization Sheath are designed to be used in place of the standard outer sheath that is supplied as part of the Evolution family of mechanical/controlled-rotation dilator sheath sets. They are provided for use in situations where better sheath tip visibility and/or tissue stabilization is desired. In its role as an Evolution outer sheath, the SteadySheath™ works in concert with the inner Evolution braided inner sheath to assist in the removal of cardiac leads or related catheters by bypassing and/or disrupting transvenous binding scar tissue. The SteadySheath™ has a highly radiopaque, textured stainless steel tip that helps stabilize tissue so that better binding scar tissue control and disruption can be achieved.

Test Data:

The modifications included in the Evolution® Mechanical Dilator Sheath Set and Evolution® Shortie Mechanical Dilator Sheath Set have already been evaluated and appropriately tested, and

have been cleared by FDA, in the context of the predicate Evolution RL Controlled-Rotation Dilator Sheath Set and Evolution Shortie RL Controlled-Rotation Dilator Sheath Set (K141148). Thus, no additional tests were required to demonstrate that the Evolution® Mechanical Dilator Sheath Set and Evolution® Shortie Mechanical Dilator Sheath Set met applicable design and performance requirements and support a determination of substantial equivalence. The following tests were performed to demonstrate that the SteadySheath™ Evolution® Tissue Stabilization Sheath and SteadySheath™ Evolution® Shortie Tissue Stabilization Sheath met applicable design and performance requirements and support a determination of substantial equivalence.

1. Push and Flex Testing – Testing was performed with the requirement that each device must remain functional after 50 cycles of flexing between 45° and 90° while within a simulated use model. The results showed that these predetermined acceptance criteria were met.
2. Push and Rotate Testing – Testing was performed with the requirement that each device must remain functional after 50 cycles of insertion, 90° rotation, and removal from a simulated use model. The results showed that these predetermined acceptance criteria were met.
3. Pull Testing – Testing was performed with the requirement that each device must withstand no less than 10 pounds of pull force prior to failure. The results showed that these predetermined acceptance criteria were met.
4. Sterility Testing – The proposed devices were evaluated for bioburden levels, endotoxin levels, and ethylene oxide and ethylene chlorohydrin residuals. Their sterility was deemed acceptable.

In conclusion, the results of these tests support a determination of substantial equivalence to the predicate devices.